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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,424	11/12/2003	Richard H. French-Constant	62,878A	5813

25212 7590 01/12/2006

DOW AGROSCIENCES LLC
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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/706,424	Applicant(s) FFRENCH-CONSTANT ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1 and 2 is/are allowed.
- 6) ☐ Claim(s) 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>search results</u> . |

DETAILED ACTION

1. Applicant's election of Group IV and nucleic acids encoding SEQ ID NO:10 in the reply filed on 17 October 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The title of the invention is not descriptive of the instantly claimed invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.
3. The abstract is not descriptive of the instantly claimed invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Claim Objections

4. Claims 3-10 and 12 are objected to because of the following informalities:
 - Claims 3-5, line 2, have an improper article before "protein".
 - Claim 5 repeats "nucleic acid" in line 1.
 - Claims 6-9 start with an improper article and are missing a comma after "5".
 - Claims 10-11 should start with an article.
 - In claim 10, an article missing before "seed".
 - In claim 12, line 3, --the group consisting of-- should be inserted after "selected" and "or" should be replaced with --and--.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A full review of the specification indicates that nucleic acids encoding TcdA1, TcdB1 and TccC2 are essential to the operation of the claimed invention. The claimed methods encompass the use of a nucleic acid encoding any TcdA1, TcdB1 and TccC2; however, the specification describes no such nucleic acids. While the prior art describes some examples of nucleic acids encoding TcdA1, TcdB1 and TccC2, the structural features that distinguish TcdA1 from other TcdA-like proteins is unclear; TcdA1 from *Photorhabdus luminescens* W14 is more similar to TcdA2 than it is to TcdA1 from *X. nematophilus* (Waterfield et al 2001, Trends Microbiol. 9:185-191; Fig 3). Similarly, the structural features that distinguish TccC2 from other TccC-like proteins is unclear; TccC2 from *P. luminescens* W14 is more similar to TccC1 from *P. luminescens* W14 than it is to TccC2 from other bacteria. Thus, the structural features that distinguish TcdA1, TcdB1 and TccC2 from other TcdA-like, TcdB-like and TccC-like proteins are not described in the prior art or the specification.

Hence, Applicant has not, in fact, described nucleic acids that encode TcdA1, TcdB1 and TccC2 within the full scope of the claims. Because the sequences are not described, the method of using the sequences to produce toxin is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

7. Claims 3-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to plants, plant cells and seeds transformed with only a nucleic acid encoding SEQ ID NO:10, which encodes TcdB2 from *Photobacterium luminescens* W14.

The instant specification, however, only provides general guidance for expression of proteins in plants; no working examples in which insect resistant plants, plant cells or seeds transformed with only a nucleic acid encoding SEQ ID NO:10 are presented.

The instant specification fails to provide guidance for how to use plants, plant cells and seeds transformed with only a nucleic acid encoding SEQ ID NO:10.

Waterfield et al (2001, Appl. Environ. Microbiol. 67:5017-5024) teach that in *S. entomophila*, which has toxin homologs to tcdA, tcdB and tccC, expression of all three is

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required to produce active toxin (paragraph spanning pg 5023-5024). This suggests that plants expressing tcdB1 (SEQ ID NO:10) alone would not be insect resistant. As Applicant provided no working examples that show that plants expressing SEQ ID NO:10 alone are insect resistant, the unpredictability suggested by the art is not overcome.

Given the claim breadth, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

In it unclear in claims 12-14 what the practitioner of the method must do to express the DNAs in a host, given that the DNAs do not have inducible promoters operably linked to them.

10. Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are promoters operably linked to each DNA to permit their expression in the host cells.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kramer et al (2001, US Patent 6,281,413).

Kramer et al teach a nucleic acid that encodes "a" protein of SEQ ID NO:10, and plants, plant cells and seeds comprising it; the plants include rice, maize, tobacco and cotton (column 8, lines 17-45; column 15, lines 33-58; column 46, line 4, to column 48, line 25; claims 1-20).

The rejection is made because a nucleic acid that encodes "a" protein of SEQ ID NO:10 includes nucleic acids that encode the full-length sequence of SEQ ID NO:10 and those that encode any portion of SEQ ID NO:10.

13. Claims 1-2 and 12-14 are free of the prior art, given the failure of the prior art to teach or suggest isolated nucleic acids encoding SEQ ID NO:10. The closest prior art is Waterfield et al (2001, Trends Microbiol. 9:185-191) and Kramer et al (2001, US Patent 6,281,413) who teach nucleic acids that encode proteins with 75.9% and 76.1% identity, respectively, to SEQ ID NO:10 (see search results).

14. Claims 1-2 are allowed.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

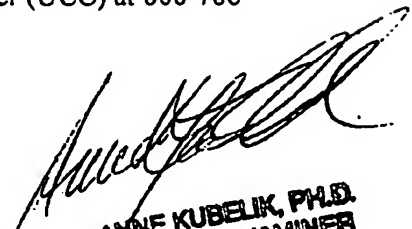
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
January 6, 2006



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER

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OM protein - protein search, using sw model

Run on: December 16, 2005, 14:28:20 , Search time 56 Seconds
(without alignments)
2176.142 Million cell updates/sec

Title: US-10-706-424-10
Perfect score: 7901
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Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 572060 seqs, 82675679 residues

Total number of hits satisfying chosen parameters: 572060

Minimum DB seq length: 0

Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : Issued Patents AA:*
1: /cgn2_6/prodata/1/iaa/5 COMB.pep.*
2: /cgn2_6/prodata/1/iaa/6 COMB.pep.*
3: /cgn2_6/prodata/1/iaa/H COMB.pep.*
4: /cgn2_6/prodata/1/iaa/PCUS COMB.pep.*
5: /cgn2_6/prodata/1/iaa/RE COMB.pep.*
6: /cgn2_6/prodata/1/iaa/baCkfilese1.pep.*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	ID	Description
1	6042	76.5	1481	2	US-09-251-645-14
2	6031.5	76.3	1476	2	US-09-817-514A-4
3	4581.5	58.0	1485	2	US-08-851-567B-32
4	160.5	2.0	1426	2	US-09-492-709A-340
5	155.5	2.0	658	2	US-09-252-991A-24910
6	155.5	2.0	2315	2	US-09-543-681A-5434
7	154	1.9	4630	2	US-09-091-609-2
8	154	1.9	5215	2	US-09-105-537-2
9	153.5	1.9	1028	2	US-09-543-681A-7181
10	144	1.8	1377	2	US-09-711-164-467
11	143	1.8	798	2	US-09-489-039A-10045
12	142.5	1.8	1183	1	US-08-447-031A-2
13	140	1.8	979	1	US-08-346-455B-38
14	140	1.8	979	2	US-08-977-221-38
15	140	1.8	979	2	US-09-483-831B-70
16	140	1.8	979	4	PCUS-0895-06613-38
17	139.5	1.8	646	2	US-09-902-540-10353
18	139.5	1.8	1577	1	US-08-793-824-2
19	139	1.8	2200	2	US-09-796-575-2
20	138	1.7	1529	2	US-09-215-694-1
21	138	1.7	1529	2	US-10-109-310-1
22	137	1.7	2628	1	US-08-570-311-14
23	136.5	1.7	990	1	US-08-232-540-2
24	136.5	1.7	990	1	US-08-428-949A-2
25	136.5	1.7	990	1	US-08-428-948A-2
26	136.5	1.7	990	1	US-08-428-946-2
27	136.5	1.7	990	4	PCUS-0895-04656-2

28	136.5	1.7	1013	1	US-08-233-008A-8	Sequence 8, Appli
29	136	1.7	1481	2	US-10-050-763-1	Sequence 1, Appli
30	135.5	1.7	667	2	US-09-328-352-4294	Sequence 4294, Ap
31	135.5	1.7	2199	2	US-08-793-273C-2	Sequence 2, Appli
32	135.5	1.7	2199	4	PCT-US95-11684-2	Sequence 2, Appli
33	135	1.7	788	1	US-08-346-455B-36	Sequence 36, Appli
34	135	1.7	788	2	US-08-977-221-36	Sequence 36, Appli
35	135	1.7	788	2	US-09-483-831B-36	Sequence 36, Appli
36	135	1.7	788	4	PCT-US95-06613-36	Sequence 36, Appli
37	134.5	1.7	1277	2	US-09-397-885-3	Sequence 3, Appli
38	134.5	1.7	1277	2	US-09-969-362-3	Sequence 3, Appli
39	133.5	1.7	1626	2	US-09-252-991A-23805	Sequence 23805, A
40	133	1.7	1665	2	US-09-543-681A-476	Sequence 476, A
41	131.5	1.7	1244	2	US-09-543-681A-6274	Sequence 6274, Ap
42	129.5	1.6	1092	2	US-09-275-608-3	Sequence 3, Appli
43	129.5	1.6	1092	2	US-09-423-126-5	Sequence 5, Appli
44	129.5	1.6	1190	2	US-09-252-991A-21474	Sequence 21474, A
45	127.5	1.6	1302	2	US-09-902-540-14853	Sequence 14853, A

ALIGNMENTS

RESULT 1
US-09-251-645-14
; Sequence 14, Application US/09251645
; Patent No. 6281413
; GENERAL INFORMATION:
; APPLICANT: Kramer, Vance C.
; APPLICANT: Morgan, Michael K.
; APPLICANT: Anderson, Arne R.
; APPLICANT: Hart, Hope
; APPLICANT: Warren, Gregory W.
; APPLICANT: Dunn, Martha
; APPLICANT: Chen, Jeng S.
; TITLE OF INVENTION: NOVEL INSECTICIDAL TOXINS FROM PHOTORHABDUS LUMINESCENS
; TITLE OF INVENTION: AND NUCLEIC ACID SEQUENCES CODING THEREFOR
; FILE REFERENCE: CGC1963/A
; CURRENT APPLICATION NUMBER: US/09/251,645
; CURRENT FILING DATE: 1999-02-17
; NUMBER OF SEQ ID NOS: 22
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 14
; LENGTH: 1481
; TYPE: PRT
; ORGANISM: Photorhabdus luminescens
US-09-251-645-14

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[illegible]